UNITED STATES PATENT APPLICATION FOR

INTERSPINOUS PROCESS APPARATUS AND METHOD WITH A SELECTABLY EXPANDABLE SPACER

INVENTORS:

James F. Zucherman
Ken Y. Hsu
Charles J. Winslow

CERTIFICATE OF MAILING BY "EXPRESS MAIL"
UNDER 37 C.F.R. §1.10

"Express Mail" mailing label number: EV 326482351 US
Date of Mailing: 10/14/03

I hereby certify that this correspondence is being deposited with the United States Postal Service, utilizing the "Express Mail Post Office to Addressee" service addressed to: **MAIL STOP PATENT APPLICATION, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450** and mailed on the above Date of Mailing with the above "Express Mail" mailing label number.

_______________(Signature)
Tina M. Galdos
Signature Date: 10/14/03

INTERSPINOUS PROCESS APPARATUS AND METHOD WITH A SELECTABLY EXPANDABLE SPACER

INVENTORS:

JAMES F. ZUCHERMAN
KEN Y. HSU
CHARLES J. WINSLOW

CLAIM OF PRIORITY

[0001] This application claims priority to U.S. Provisional Application No. 60/421,921, filed on October 29, 2002, entitled "INTERSPINOUS PROCESS APPARATUS AND METHOD WITH A SELECTABLY EXPANDABLE SPACER" (Attorney Docket No. KLYC-01056USC), which is incorporated herein by reference.

CROSS-REFERENCE TO PREVIOUSLY FILED RELATED APPLICATIONS AND PATENTS

[0002] This application is related to U.S. Patent Application Serial No. 10/037,236, filed on November 9, 2001, which is related to U.S. Patent Application Serial No. 09/799,215, filed on March 5, 2001, which is a related to U.S. Patent Application Serial No. 09/179,570, filed on October 27, 1998, now U.S. Patent 6,048,342, which is related to U.S. Patent Application Serial No. 09/175,645, filed on October 20, 1998, now U.S. Patent 6,068,630. This application is also related to U.S. Patent No. 5,836,948, issued November 17, 1998 and U.S. Patent No. 5,860,977, issued January 19, 1999. All of the above are incorporated herein by reference.

FIELD OF THE INVENTION

[0003] This invention relates to an apparatus and method for adjustably distracting the spinous process of adjacent vertebrae.

Background of the Invention

[0004] The spinal column is a bio-mechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The bio-mechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk, and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and the nerve roots.

[0005] As the population ages, it is anticipated that there will be an increase in adverse spinal conditions characteristic in older persons. For example, with aging comes an increase in spinal stenosis (including, but not limited to, central canal and lateral stenosis), the thickening of the bones that make up the spinal column, and facet antropathy. Spinal stenosis is characterized by a reduction in the available space for the passage of blood vessels and nerves. Pain associated with such stenosis can be relieved by medication and/or surgery. Of course, it is desirable to eliminate the need for major surgery for all individuals, and, in particular, for the elderly.

[0006] In addition, there are a variety of other ailments that can cause back pain in patients of all ages. For these ailments it is also desirable to eliminate such pain without major surgery.

[0007] Accordingly, there is a need for a method for alleviating such conditions that is minimally invasive, can be tolerated by patients of all ages (in particular, the elderly), can be performed on an out-patient basis, and allows adjustments both during and after surgery to minimize

patient discomfort. There is a further need for an apparatus with which to apply the method.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] **FIGS. 1A-1F**. **FIG. 1A** is a front plan view of one embodiment of an apparatus with a selectably expandable spacer; **FIG. 1B** is a left side view of the apparatus of **FIG. 1A**; **FIG. 1C** is a front plan view of the apparatus of **FIG. 1A** including a selectably expandable spacer, a main body and a first wing; **FIG. 1D** is a left side view of the second wing of the apparatus of **FIG. 1A**; **FIG. 1E** is a front plan view of the second wing of the apparatus of **FIG. 1A**; **FIG. 1F** is an end view of the selectably expandable spacer of the apparatus of **FIG. 1A**

[0009] **FIGS. 2A** and **2B**. **FIG. 2A** is a right side view of an embodiment of the selectably adjustable spacer in an unexpanded position. **FIG. 2B** is a right side view of an embodiment of the selectably adjustable spacer in a fully expanded position.

[0010] **FIGS. 3A** and **3B**. **FIG. 3A** is a right side cross-sectional view of an embodiment of the selectably adjustable spacer in an unexpanded position. **FIG. 3B** is a left side cross-sectional view of an embodiment of the selectably adjustable spacer in a fully expanded position.

[0011] **FIG. 4** is a front side view of an embodiment of the selectably adjustable spacer.

[0012] **FIG. 5A** is a perspective view of an embodiment of the selectably adjustable spacer. **FIG. 5B** is a back view of another embodiment of the spacer similar to that shown in **FIG. 5A** with a mechanism for allowing the spacer to expand.

[0013] **FIGS. 6A** and **6B.** **FIG. 6A** is a right side view of an alternative embodiment of the selectably expandable spacer with a jack expansion mechanism in an unexpanded position. **FIG. 6B** is a right side

view of an alternative embodiment of the selectably expandable spacer with a jack expansion mechanism in a fully expanded position.

[0014] **FIG. 7** is a block diagram demonstrating the steps for performing the method.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0015] The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. To the extent necessary to achieve a complete understanding of the invention disclosed, the specification and drawings of all patents and patent applications cited in this application are incorporated herein by reference.

[0016] **FIGS. 1A-1F** illustrate an embodiment of an apparatus, or implant ***100***, suitable for use with the method of this invention. The implant ***100*** includes a first wing ***104***, a selectably expandable spacer ***150*** and a lead-in tissue expander or distraction guide ***110***. The implant further includes, as required, a second wing ***132***. As can be seen in **FIG. 1A**, a shaft ***102*** extends from the first wing ***104*** and is the body that connects the first wing to the distraction guide ***110***. Also, as can be seen in **FIGS. 1A** and **1B**, the guide ***110*** in this particular embodiment is pointed in order to allow the implant to be inserted between, and, if necessary, to distract adjacent spinous processes. In this particular embodiment, the guide ***110*** has a wedge-shaped cross-section,

expanding from the distal end ***111*** to the area where the second wing ***132*** can be optionally secured to the guide. **FIGS. 1B** and **1C** illustrate an embodiment of the implant ***100*** with only a first wing ***104***.

[0017] As required, implant ***100*** can include a second wing ***132*** which fits over the guide ***110*** and is secured by a bolt ***130*** placed through aperture ***134*** of the second wing ***132*** to the threaded bore ***112*** located in the guide ***110***. As implanted, the first wing ***104*** is located adjacent to first sides of the spinous processes and the second wing ***132*** is located adjacent to second sides of the same spinous processes.

[0018] The spacer ***150*** is rotatably mounted about a shaft ***102***. The spacer ***150*** is positioned between the first wing ***104*** and the guide ***110***. The tissue expander ***110*** guides the spacer ***150*** into position between the spinous process of adjacent vertebrae. The spacer ***150*** includes a slotted sphere ***151*** that when rotated is positioned along a lead-screw, expanding or collapsing the spacer.

[0019] **FIGS. 1F, 2A-B, 3A-B,** and **5** illustrate a preferred embodiment of the spacer ***150*** wherein the shape of the spacer ***150*** is oval or elliptical in cross-section, although it can alternatively be circular or ovoid or race-track shaped in cross-section. It is to be understood that the spacer ***150*** can have other shapes as described throughout the specification and be within the spirit and scope of the invention. In a preferred embodiment, the spacer ***150*** includes a bore ***152*** extending the length of the spacer ***150***. The bore ***152*** of the spacer ***150*** is received over the shaft ***102*** of the implant ***100*** so that, as described above, the spacer can be rotated about the shaft ***102***. In these embodiments, the spacer ***150*** can have minor and major dimensions as follows:

Minor Dimension (116a)	Major Dimension (116 b)
6 mm	10 mm
8 mm	10.75 mm
12 mm	14 mm
6 mm	12.5 mm
8 mm	12.5 mm
10 mm	12.5 mm

[0020] One advantage of the use of the spacer ***150***, as depicted in the embodiment of **FIG. 1A**, is that the spacer ***150*** can be partially rotated and repositioned with respect to the first wing ***104*** in order to optimize positioning of the implant ***100*** between spinous processes. It is to be understood that the cortical bone or the outer bone of the spinous processes is stronger at an anterior position adjacent to the vertebral bodies of the vertebra than at a posterior position distally located from the vertebral bodies. Also, biomechanically for load bearing, it is advantageous for the spacer ***150*** to be close to the vertebral bodies. In order to facilitate this and to accommodate the anatomical form of the bone structures, as the implant is inserted between the spinous processes and/or urged toward the vertebral bodies, the spacer ***150*** rotates relative to the wings, such as wing ***104***, so that the spacer ***150*** is optimally positioned between the spinous processes, and the wing ***104*** is optimally positioned relative to the spinous processes.

[0021] In another embodiment, the spacer ***150*** has a cross-section with a major dimension and a minor dimension, wherein the major dimension is greater than the minor dimension, and, for example, less than about two times the minor dimension. It is to be understood that the spacer ***150*** can be fabricated from somewhat flexible and/or deflectable material.

[0022] In this embodiment the spacer is made out of a polymer, more specifically, the polymer is a thermoplastic. Still more specifically, the polymer is a polyketone known as polyetheretherketone (PEEK™).

Still more specifically, the material is PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. (Victrex is located at www.matweb.com or see Boedeker www.boedeker.com). Other sources of this material include Gharda located in Panoli, India (www.ghardapolymers.com).

[0023] The spacer ***150*** can be formed by extrusion, injection, compression molding and/or machining techniques. This material has appropriate physical and mechanical properties and is suitable for carrying and spreading the physical load between the spinous process. For example, in this embodiment, the PEEK has the following approximate properties:

Density	1.3 g/cc
Rockwell M	99
Rockwell R	126
Tensile Strength	97 MPa
Modulus of Elasticity	3.5 GPa
Flexural Modulus	4.1 Gpa

[0024] It should be noted that the material selected may also be filled. For example, other grades of PEEK are also available and contemplated, such as 30% glass-filled or 30% carbon-filled, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that which is unfilled. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon-filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon-filled PEEK offers wear resistance and load carrying capability.

[0025] In this embodiment, as described above, the spacer ***150*** is manufactured from polyetheretherketone (PEEK™), available from

Victrex. As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable, have very low moisture absorption, and good wear and/or abrasion resistance, can be used without departing from the scope of the invention. The spacer can also be comprised of polyetherketoneketone (PEKK).

[0026] Other materials that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and generally a polyaryletheretherketone. Further other polyketones can be used as well as other thermoplastics. The spacer can also be made of titanium.

[0027] Reference to appropriate polymers that can be used in the spacer can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated January 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials."

[0028] Other materials such as Bionate®, polycarbonate urethane, available from the Polymer Technology Group, Berkeley, California, may also be appropriate because of the good oxidative stability, biocompatibility, mechanical strength and abrasion resistance. Other thermoplastic materials and other high molecular weight polymers can be used.

[0029] A preferred embodiment of the spacer is illustrated in **FIGS. 2A-5**. In **FIGS. 2A** and **2B** the spacer ***150*** includes a first portion ***260*** pivotably or rotatably coupled with a second portion ***261*** by a hinge (shown in **FIG. 4**). Both the first portion ***260*** and the second portion ***261*** have tapered distal ends that form an acute angle between the two

portions. **FIG. 2A** illustrates the acute angle ***265a*** formed when the spacer ***150*** is in the unexpanded position. The first portion ***260*** has a bore ***252*** through which the shaft ***102***, shown in **FIG. 1A**, is received, connecting the first wing ***104*** with the guide ***110*** and connecting the spacer ***150*** with the implant ***100***. The bore ***252*** allows the spacer ***150*** to partially rotate about the shaft ***102***. The second portion ***261*** of the spacer ***150*** also has a bore that is located behind and aligned with the bore ***252***, shown in **FIG. 2A**. This bore is also received on the shaft ***102*** so that both the first and second portions of the spacer ***150*** can rotate about the shaft ***102***. A threaded screw ***253*** protrudes through the angle ***265a*** formed by the tapered distal ends of the portions. The end of the threaded screw ***253*** also has a bore that aligns with the bores of the first and second portions of the spacer ***150*** and is received on the shaft ***102*** and can rotate about the shaft ***102***. A slotted sphere ***151*** is connected with the distal end of screw ***253***. In the least expanded position, the slotted sphere ***151*** is at the farthest point of travel away from the proximal end of the screw ***253*** **FIG. 2A.**

[0030] **FIG. 2B** illustrates the acute angle ***265b*** formed when the spacer ***150*** is in the fully expanded position. The slotted sphere ***151*** is rotated such that the sphere travels toward the proximal end of the threaded screw ***253***. As the slotted sphere ***151*** travels toward the proximal end of the screw ***253***, the sphere ***151*** forces the tapered distal ends of the portions ***260***, ***261*** apart. As the distal ends of the portions are forced apart, the first portion ***260*** and the second portion ***261*** rotate in opposite directions about a common hinge ***463*** (shown in **FIG. 4**), sliding along the contact surface ***262***. As the acute angle formed by the distal ends of the portions increases, the height of the spacer ***150*** expands.

[0031] **FIGS. 3A** and **3B** illustrate in cross-section the preferred embodiment of the selectably expandable spacer described in reference to **FIGS. 2A** and **2B**. The slotted sphere ***151*** has a threaded cavity for

receiving the threaded screw ***253*** when the sphere ***151*** is rotated. The slotted sphere ***151*** travels the distance ***351c*** such that the distal end of the screw ***253*** moves from position ***351a*** to position ***351b*** along the threaded cavity of the sphere when adjusted from an unexpanded to a fully expanded position. When rotated in the opposite direction, the slotted sphere ***151*** moves away from the proximal end of the screw ***253***, collapsing the spacer ***150***. **FIG. 3B** illustrates the spacer ***150*** in a fully expanded position with the distal end of the screw ***253*** at the maximum position ***351b*** in the threaded cavity of the slotted sphere ***151.*** It is to be understood that portions the ***260, 261*** of the spacer ***150*** can be biased to the closed position shown in **FIG. 3A.** The biasing can be accomplished by a spring that is coiled in or about the bore of the spacer that receives the shaft ***102***. Such a spring would be connected to both of the portions ***260, 261*** of the spacer ***150***.

[0032] The first and second portions of the spacer ***150*** in combination, can have a cross-section that is elliptical, oval, ovoid, football-shaped, circular-shaped, rectangular with rounded ends (where the cross-section has two somewhat flattened surfaces and two rounded surfaces similar to the effect of a flattened ellipse) or race-track shaped. Further, the first and second portions can have different cross-sectional shapes relative to each other. At least the minor dimension (the height) of the spacer is between 6 mm and 14 mm. Typically, the minor outer dimension is one of 6 mm, 8 mm, 10 mm, 12 mm, and 14 mm. The different sizes and selectable expandability enable the spacer to accommodate different sized patients.

[0033] As discussed above, the spacer ***150*** and its components, including either the first or second portions, or both, can be made of a number of materials. Suitable materials can include polymers, such as, for example, polyetheretherketone (PEEK™), as well as other materials described above, including titanium. Such materials can be deflectable and flexible depending on the configuration of the spacer ***150***.

[0034] Further, the deflectable or flexible material can have a graduated stiffness to help gradually distribute the load when the spinous processes place a force upon the exterior surface of the spacer. This can be accomplished by forming multiple layers of the deflectable or flexible material with decreasing stiffness or hardness from the center of the spacer outwardly. Alternatively, the material can have a higher stiffness or hardness in the center of the inner spacer.

[0035] Referring to **FIG. 4**, the slotted sphere ***151*** is positioned approximately equidistant from a first and second ends of the spacer ***150***, distributing the parting force of the sphere ***151*** so as not to create disproportionate stress on either side of the spacer ***150***.

[0036] A hinge ***463*** couples a first portion ***260*** with a second portion ***261***, such that the two portions pivot about the hinge ***463***, expanding or collapsing the gap ***465***.

[0037] A perspective view is provided in **FIG. 5A**, showing the clam-shape of the preferred embodiment of the spacer ***150***. The implant ***100*** is positioned between the adjacent vertebrae so as to permit access to the slot ***554*** from a posterior direction both during and after surgery. Post-surgery adjustment is made using a cannula inserted through the patient's back. Convenient access to the slot ***554*** is important for reducing patient discomfort and procedure complication.

[0038] The bore ***252*** provides a sleeve for the shaft ***102***, and also limits the rotation of the spacer ***150*** about the shaft ***102***. Limiting the rotation of the spacer ***150*** can be accomplished, for example, by providing a slot ***255*** in the bore ***252*** and a key on the shaft ***102***, or vice-versa. One of skill in the art can appreciate that different mechanisms and geometries can be used to limit spacer rotation. Reference is also made to a copending U.S. patent application entitled "Spinal Implants, Insertion Instruments, and Methods of Use," filed on March 5, 2001, as U.S. Patent Application Serial No. 09/799,470 (KLYC-1027US1), which

is incorporated herein by reference and which discloses an implant which has a spacer with a slot and an implantation tool that includes a probe that engages the slot in order to position the spacer relative to the implantation tool for desirable initial positioning of the space relative to the spinous processes. Such a mechanism can be used by itself or in addition to the above discussed keyway and key for purposes of positioning the sphere ***151*** so that the height of the spacer ***150*** can be selectively adjusted during the initial surgical procedure or, thereafter, should such adjustment be desirable due, for example, to the need for more distraction between the spinous processes.

[0039] **FIG. 5B** depicts the back of another embodiment of the spacer ***150*** of the implant ***100*** of the invention. **FIG. 5B** is similar to a back view of the embodiment depicted in **FIG. 4**. In **FIG. 5B**, the spacer ***150*** includes the first and second portions ***260, 261***, respectively. The first portion includes a bore ***252*** that receives the shaft ***102*** and the second portion includes bore ***254*** that also receives the shaft ***102***. In addition, the screw ***253*** is shown with a portion of the sphere ***151*** that is used to adjust the height of the spacer ***150***. The screw ***253*** includes a bore ***257*** that also receives the shaft ***102***. Thus, the first and second portions of the spacer and the screw are rotatable about the shaft.

[0040] One of skill in the art can also appreciate the different expansion mechanisms that can be employed to expand the spacer ***150***. For example, an expansion mechanism could include: pistons, ratchets, cams, jacks, or other machines. **FIGS. 6A** and **6B** illustrate one alternative embodiment in which a jack ***651*** is used to expand the spacer ***150***. The jack ***651*** is expanded or collapsed by rotating a slotted screw ***653***, thereby increasing or decreasing the gap ***665***. **FIG. 6A** shows the spacer ***150*** in an unexpanded position with a narrow gap ***665a***.

[0041] **FIG. 6B** illustrates another alternative embodiment utilizing a jack, whereby the hinge ***462*** can allow for translation of the first and

second portions in the y-direction as well as for rotation about the hinge ***462***, thereby reducing the stresses on the side of the jack closest to the hinge caused by uneven compression when the gap ***665b*** expands. For the embodiment in **FIGS. 6A** and **6B** any of the above devices for allowing the first portion of the spacer to move relative to the second portion of the spacer can be employed, as well as other known methods, and be within the spirit and scope of the invention.

[0042] The preferred method for inserting the implant between adjacent vertebrae is block-diagramed in **FIG. 7**. The method requires that the spine be surgically exposed. The implant is then inserted between the spinous processes, with the wedge shape of the guide forcing tissue apart to create room for the implant. Once the implant is in place, with the spacer between adjacent vertebrae, the profile of the implant is adjusted by expanding or collapsing the spacer using a tool for operating the expansion mechanism. The wound is then closed.

[0043] The implant can subsequently be readjusted with the insertion of a cannula through which a tool is inserted for operating the expansion mechanism.

[0044] The embodiment of this apparatus as well as the several other apparatuses described herein, act to limit extension (backward bending) of the spine. These apparatuses, however, do not inhibit the flexion (forward bending) of the spinal column.

[0045] The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and

with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalence.